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PERKINS, SMITH & COHEN LLP ONE BEACON STREET 30TH FLOOR BOSTON, MA 02108			JIANG, SHAOJIA A	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/033,149

Applicant(s)

MASON, R. PRESTON

Examiner

Shaojia A. Jiang

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 29-65 is/are pending in the application.
- 4a) Of the above claim(s) 29-56 and 60-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 57-59 and 63-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This Office Action is in response to Applicant's amendment and response filed on February 7, 2005 wherein claims 1-6, 57-59, and 63-68 have been amended, Note that claims 58-59 are missing in the list of claims in Applicant's amendment herein. Claims 7-14 and 22-28 are cancelled previously.

Currently, claims 1-6, 29-56, 57-59, and 60-65 are pending in this application.

It is noted that claims 29-56 and 60-62 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, of record in the previous Office Action dated November 4, 2004.

Claims 1-6, 57-59, and 63-68 as amended now are examined on the merits herein.

The following is the new ground(s) of rejection(s).

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 57-59, and 63-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had full possession of the claimed invention.

The claims herein are drawn to the use of any therapeutic agents represented by "hydroxylated atorvastatin metabolite". Thus, the recitation in the claims are deemed to a broad genus of any compounds represented by "hydroxylated atorvastatin metabolite" which would reasonably be interpreted as any atorvastatins hydroxylated in any positions in atorvastatin and any atorvastatin metabolites.

The specification as originally filed does not provide adequate support for a generic claims herein. The specification merely describes a single specific compound (see its structure at Fig 4A). The specification has not taught any other hydroxylated atorvastatin metabolites are intended to be encompassed within the scope of claims.

The CAFC further clearly states that "[A] written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials" at 1405(emphasis added), and that "It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus." at 1406 (emphases added).

More over, the court of *In re Curtis* held that "a patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability ....of any other species." (emphasis added, see *In re Curtis* 354 F.3d 1347, 69 USPQ2d 1274, Fed. Cir. 2004). The court of *Noelle v. Lederman* also pointed out

that generic claim to anti-CD40CR Mabs lacked written description support because there was no description of anti-human or other species Mabs, and no description of human CD40CR antigen. The court further pointed out that attempt to "define an unknown by its binding affinity to another unknown" failed. See 355 F.3d 1343, 69 USPQ2d 1508, Fed. Cir. 2004.

In this case, the claimed composition herein is deemed not to adequately described. Thus, ordinary artisans could not predict the operability of any other species of "hydroxylated atorvastatin metabolite". Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in full possession of the invention as it is now claimed.

Claims 1-6, 57-59, and 63-68 as amended now are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted February 7, 2005 with respect to amended claims herein has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for "a substantially pure form". Nowhere can the recitation "a substantially pure form" of "hydroxylated atorvastatin metabolite" be found in the specification.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6, 57-59 and 63-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Buch (US 6,455,574, PTO-892).

Buch discloses a composition comprising the combination of an effective amount of amlodipine or its pharmaceutically acceptable salt, amlodipine besylate, and an effective amount of atorvastatin calcium or its pharmaceutically acceptable salt (which reads on “hydroxylated atorvastatin metabolite”, for treating the same diseases as instantly claimed such as hypertension, hyperlipidemia, atherosclerosis, arteriosclerosis, coronary artery disease, myocardial infarction, congestive heart failure, stroke, and angina pectoris (see abstract, col.1-4; claims 1-12). Atorvastatin calcium is known for administering to a human in “a substantially pure form”.

Note that a pharmaceutically acceptable salt of atorvastatin would read on “hydroxylated atorvastatin metabolite”. Moreover, hydroxylated atorvastatin metabolite claimed herein is a metabolite of atorvastatin, which was necessarily produced in the patient’s body upon ingestion of atorvastatin. Note that the court ruled that the metabolite of loratadine called descarboethoxyloratadine or “DCL” was INHERENTLY anticipated by loratadine (Claritin <sup>TM</sup>) because it was necessarily produced in the patient’s body upon ingestion of Claritin <sup>TM</sup>. See Schering Corp. v. Geneva Pharmaceuticals, Inc., 68 USPQ2d 1760 (CAFC 2003). Thus, atorvastatin disclosed by the Pfizer News would anticipate hydroxylated atorvastatin metabolite. Moreover, the tablets of Norvasc and Lipitor are known to comprise pharmaceutical acceptable carriers or diluents.

Thus, the disclosure of Buch anticipates the instant claimed composition.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 68 is rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling the combination of amlodipine and atorvastatin metabolite further comprising the particular and specific antioxidant, does not reasonably provide enablement for any substances or compounds

represented by "an endogenous and/or exogenous antioxidant" for the same reasons of record in the previous Office Action November 4, 2004.

The recitation, "an endogenous and/or exogenous antioxidant" is seen to be merely functional language.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation as discussed in the previous Office Action.

### ***Response to Argument***

Applicant's arguments filed February 7, 2005 with respect to this rejection made under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement have been fully considered but are not deemed persuasive as further discussed below.

Applicant argues that both endogenous and/or exogenous antioxidants are well known to those skilled in the art at the time the invention was made. Applicant's argument has been considered but not found convincing. As noted in MPEP 2111, during patent examination, claims are given their **broadest** reasonable interpretation.

In this case, In this case, the instant claims are **not limited** to those particular known endogenous and/or exogenous antioxidants in the art. On the contrary the instant claims read on administering to any endogenous and/or exogenous antioxidants.

The specification fails to provide clear and convincing evidence in sufficient support of the administration to a human or *vitro* testing the **combination** of amlodipine



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and atorvastatin metabolite and any substance or compound represented by “an endogenous and/or exogenous antioxidant”. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any known and unknown antioxidants encompassed in the instant claims suitable to practice the claimed invention as indicated in the previous Office Action.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, side effects, and especially serious toxicity that may be generated by drug-drug interactions when and/or after administering to a host (i.e., a mammal) the combination of amlodipine and atorvastatin metabolite and any substance or compound represented by “an endogenous and/or exogenous antioxidant”. See text book “Goodman & Gilman's The Pharmacological Basis of Therapeutics” regarding possible drug-drug interactions (9<sup>th</sup> ed, 1996) page 51 in particular. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

Therefore, the skilled artisan has to exercise **undue experimentation** to practice the instant invention.

For the above stated reasons, said claims are properly rejected made under 35 U.S.C. 112, first paragraph, for lack of full scope of enablement.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 and 58-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the same reasons of record in the previous Office Action November 4, 2004.

### ***Response to Argument***

Applicant's arguments filed February 7, 2005 with respect to this rejection made under 35 U.S.C. 112, second paragraph, for use of indefinite recitations as further discussed below.

The recitation, "derivative of amlodipine" render claims 2-3 and 58-59 indefinite. The recitation, "derivative of amlodipine " is not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to " derivative of amlodipine ", since one of ordinary skill in the art would clearly recognize that that " derivative of amlodipine " read on many widely varying groups possibly substituting amlodipine. Given the fact that any significant structural variation to a compound would be reasonably expected to alter its properties, e.g., physical, chemical, physiological effects and functions.

Thus, it is unclear as to "derivative of amlodipine" herein encompassed thereby.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 57-59 and 63-67 are rejected under 35 U.S.C. 102(b) as being anticipated by the Pfizer News, May 20, 1997 of record in the previous Office Action November 4, 2004.

The Pfizer News discloses the combination of Norvasc also known as amlodipine besylate (See FDA approval February 7, 1995, PTO-892) and Lipitor also known as atorvastatin calcium in their effective amounts for treating cardiovascular diseases (see the 4<sup>th</sup> paragraph of page 2 of Pfizer News). Hydroxylated atorvastatin metabolite claimed herein is a metabolite of atorvastatin, which was necessarily produced in the patient's body upon ingestion of atorvastatin. Note that the court ruled that the metabolite of loratadine called descarboethoxyloratadine or "DCL" was INHERENTLY anticipated by loratadine (Claritin <sup>TM</sup>) because it was necessarily produced in the patient's body upon ingestion of Claritin <sup>TM</sup>. See Schering Corp. v. Geneva Pharmaceuticals, Inc., 68 USPQ2d 1760 (CAFC 2003). Thus, atorvastatin disclosed by the Pfizer News would anticipate hydroxylated atorvastatin metabolite. Moreover, the tablets of Norvasc and Lipitor are known to comprise pharmaceutical acceptable carriers or diluents. Atorvastatin is known for administering to a human in "a substantially pure form"; thus hydroxylated atorvastatin metabolite produced in the body is also deemed in "a substantially pure form".

Further, note that it is well settled that "intended use" of a composition or product, e.g., the recitation, "inhibit lipid peroxidation in human LDL or lipid membrane to achieve

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a therapeutic effect", will not further limit claims drawn to a composition or product, so long as the prior art discloses the same composition comprising the same ingredients in an effective amount as the instantly claimed. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161. Note that the combination of the prior art cited herein would certainly inhibit lipid peroxidation in human LDL or lipid membrane to achieve a therapeutic effect

Thus, the combination of the prior art cited herein anticipates the instant claimed composition.

### ***Response to Argument***

Applicant's arguments filed February 7, 2005 with respect to the rejection made under 35 U.S.C. 102(b) of record in the previous Office Action have been fully considered but are not deemed persuasive as to render the claimed invention patentable over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buch (US 6,455,574) or the Pfizer News, May 20, 1997 in view of Gilligan et al. (Journal of the American College of Cardiology, (1994 Dec) 24 (7) 1611-7).

The same disclosure of Buch (US 6,455,574) or the Pfizer News has been discussed in the 102(b) rejection set forth above.

The News does not expressly disclose the combination therein further comprising an antioxidant.

Gilligan et al. teaches that antioxidants such as Vitamin A, C, and E, are known to be used in the treatment of hypercholesterolemia in humans. See the abstract and entire article.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to further employ antioxidants such as Vitamin A, C, and E in the composition for treating hypercholesterolemia or atherosclerosis.

One having ordinary skill in the art at the time the invention was made would have been motivated to further employ antioxidants such as Vitamin A, C, and E in the composition for treating hypercholesterolemia or atherosclerosis since the combination of amlodipine and atorvastatin, and antioxidants such as Vitamin A, C, and E are known to be used in the treatment of hypercholesterolemia in humans according to the prior art cited herein.

Therefore, one of ordinary skill in the art would have reasonably expected that adding an antioxidant such as Vitamin A, C, and E to the combination of amlodipine and atorvastatin would improve the anti-lipidemia effect of the combination.

Since all active composition components herein are known, it is considered prima facie obvious to combine them into a single composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

### ***Response to Argument***

Applicant's arguments filed February 7, 2005 with respect to the rejection made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicant argues that there is no motivation or suggestion to add an antioxidant such as Vitamin A, C, and E to the combination of amlodipine and atorvastatin. Applicant's argument has been considered but is not found persuasive. It is noted that "the rationale to modified or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or implied contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law." (see MPEP 2144, citing *In re fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1988), for example).

It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for same purpose in order to form a third composition that is to be used for the very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205

USPQ 1069, CCPA 1980. See MPEP 2144.06. In the instant case, as discussed in the set forth 103(a) rejection above, one of ordinary skill in the art would have reasonably expected that adding an antioxidant such as Vitamin A, C, and E to the combination of amlodipine and atorvastatin would improve the anti-lipidemia effect of the combination.

The record contains no clear and convincing evidence of nonobviousness or unexpected results for the combination of an antioxidant such as Vitamin A, C, and E and amlodipine and atorvastatin over the prior art. For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6, 57-59 and 63-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 118-147 of copending Application No. 10/214,058.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the copending application and the instant claims are drawn to a pharmaceutical composition comprise amlodipine and atorvastatin.

Thus, the instant claims 1-3 and 118-147 are deemed to be anticipated by the claims 1-3 and 118-147 of copending Application No. 10/214,058.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-6, 57-59 and 63-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 84-86 and 118-192 of copending Application No. 10/637781.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a pharmaceutical composition comprise the same combination of amlodipine and atorvastatin while the copending application is drawn to a pharmaceutical kit comprise amlodipine and atorvastatin in two separate dosage forms, and container and directions for the administration of the two dosage forms.

Since the employment of a pharmaceutical kit or the patient pack comprising the same combination pharmaceutical composition in two dosage forms and directions for administering the dosage forms are all deemed obvious since they are all within the knowledge and conventional skills of pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication. Moreover, the inclusion of a package



inserts including "indication and use" of the pharmaceutical composition in a pharmaceutical kit is mandated by 21 CFR 201.57 according to *Remington: The Science and Practice of Pharmacy*. Furthermore, with respect to the instructions or directions that direct one on how to use in a kit, the U.S. Court of Appeals for the Federal Circuit, *In re Ngai* 03-1524, recently rules that a kit of the prior art with a set of instructions is unpatentable (see the precedential opinion issued May 13, 2004).

Thus, the instant claims -6, 57-59 and 63-67 are deemed to be obvious over the claims 84-86 and 118-192 of copending Application No. 10/637781.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments regarding to these obviousness-type double patenting rejections have been considered but not found persuasive. Applicant is suggested to address whether there is common assignee(s) or commonly owned between the instant application and the copending applications.

In view of the rejections to the pending claims set forth above, no claims are allowed.

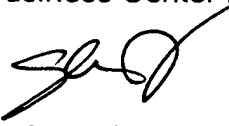
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The

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fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



S. Anna Jiang, Ph.D.  
Primary Examiner  
Art Unit 1617  
April 27, 2005